JP 60-70324
Equivalent

Title:

Implantable telemetric medical sensor and method

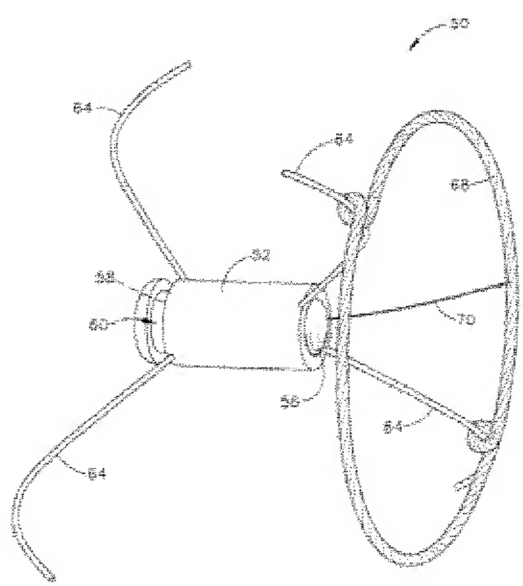
Document Type and Number:

United States Patent 6638231

Abstract:

A telemetric medical sensor for implantation in a patient's body for measuring a parameter therein is provided. The sensor comprises a housing and a membrane at one end of the housing. The membrane is deformable in response to the parameter being measured. A microchip is positioned within the housing and operatively communicates with the membrane for transmitting a digital signal indicative of the parameter. The microchip comprises an array of photoelectric cells for use with an LED for transmitting light at the photoelectric cells. A shutter is connected to the membrane and moveable between the photoelectric cells and the LED in response to deforming of the membrane.

Representative Image:



Inventors:

Govari, Assaf (Haifa, IL)
Ben-haim, Shlomo (Haifa, IL)
Zilberstein, Joel (Haifa, IL)
Capezzuto, Louis J. (Monroe, NJ)

Application Number: 09/739053

Publication Date: 10/28/2003

Filing Date: 12/18/2000

View Patent Images: Images are available in PDF form when logged in. To view PDFs, **Login** or **Create Account (Free!)**

Referenced by: **View patents that cite this patent**

Export Citation: **Click for automatic bibliography generation**

Assignee: Biosense, Inc. (New Brunswick, NJ)

Primary Class: **600/486**

International Classes: ***A61B5/00***; *A61B5/07*; A61B5/02

Field of Search: 128/899, 600/488, 600/483, 600/300, 607/27, 607/18, 600/484, 600/485, 600/462, 600/561, 600/486, 600/505, 607/2, 600/317, 600/487, 600/509, 600/301, 607/9, 128/903, 600/480

US Patent References:

3672352	IMPLANTABLE BIO-DATA MONITORING METHOD AND APPARATUS	Summers	
4114151	Passive transponder apparatus for use in an interrogator-responder system	Denne et al.	
4198987	Measuring system including elements implantable beneath the skin	Cain et al.	
RE30366	Organ stimulator	Rasor et al.	
4262632	Electronic livestock identification system	Hanton et al.	
4361153	Implant telemetry system	Slocum et al.	
4407296	Integral hermetic impantable pressure transducer	Anderson	
4485813	Implantable dynamic pressure transducer system	Anderson et al.	
4532932	Implant communication system with frequency shift means	Batty, Jr.	
4610256	Pressure transducer	Wallace	600/488
	Apparatus for locating		

4621628	transverse holes of intramedullary implantates	Brudermann	
4650547	Method and membrane applicable to implantable sensor	Gough	
4796643	Medical electrode leads	Nakazawa et al.	
4815469	Implantable blood oxygen sensor and method of use	Cohen et al.	
4846191	Device for chronic measurement of internal body pressure	Brockway et al.	
4967755	Electromedical lead with pressure sensor	Pohndorf	
5028918	Identification transponder circuit	Giles et al.	
5067491	Barrier coating on blood contacting devices	Taylor, II et al.	600/561
5105190	Electromagnetic identification system	Kip et al.	
5105829	Surgical implement detector utilizing capacitive coupling	Fabian et al.	
5127913	Apparatus and method for implanting an intramedullary rod	Thomas, Jr.	
5252962	System monitoring programmable implantable transponder	Urbas et al.	
5279309	Signaling device and method for monitoring positions in a surgical operation	Taylor et al.	
5300120	Implant with electrical transponder marker	Knapp et al.	
5322063	Hydrophilic polyurethane membranes for electrochemical glucose sensors	Allen et al.	
5325873	Tube placement verifier system	Hirschi et al.	
5330520	Implantable electrode and sensor lead apparatus	Maddison et al.	
5353800	Implantable pressure sensor lead	Pohndorf et al.	
5398691	Method and apparatus for three-dimensional translumenal ultrasonic imaging	Martin et al.	
5404877	Leadless implantable sensor assembly and a cardiac emergency warning alarm	Nolan et al.	
	Instrumentation for distal		

5411503	targeting of locking screws in intramedullary nails	Hollstien et al.	
5417688	Optical distal targeting system for an intramedullary nail	Elstrom et al.	
5422636	System monitoring programmable implantable transponder	Urbas et al.	
5435310	Determining cardiac wall thickness and motion by imaging and three-dimensional modeling	Sheehan et al.	
5481262	System monitoring programmable implanatable transponder	Urbas et al.	
5513636	Implantable sensor chip	Palti	
5540691	Optical distal targeting method for an intramedullary nail	Elstrom et al.	
5551427	Implantable device for the effective elimination of cardiac arrhythmogenic sites	Altman	
5564434	Implantable capacitive absolute pressure and temperature sensor	Halperin et al.	
5566676	Pressure data acquisition device for a patient monitoring system	Rosenfeldt et al.	
5584838	Distal targeting system	Rona et al.	
5674288	Implant with transponder marker	Knapp et al.	
5702421	Closure device for closing a vascular opening, such as patent ductus arteriosus	Schneidt	
5704352	Implantable passive bio-sensor	Tremblay et al.	
5715827	Ultra miniature pressure sensor and guide wire using the same and method	Corl et al.	600/486
5716407	Method of rendering identifiable a living tissue implant using an electrical transponder marker	Knapp et al.	
5725552	Percutaneous catheter directed intravascular occlusion devices	Kotula et al.	
5725578	Temporary implant with transponder and methods for locating and indentifying	Knapp et al.	
5743267	System and method to monitor the heart of a patient	Nikolic et al.	

5833603	Implantable biosensing transponder	Kovacs et al.	600/317
5855609	Medical information transponder implant and tracking system	Knapp	
5879366	Self-expanding defect closure device and method of making and using	Shaw et al.	
5913820	Position location system	Bladen et al.	
5957966	Implantable cardiac lead with multiple shape memory polymer structures	Schroeppel et al.	
5963132	Encapsulated implantable transponder	Yoakum	
5977431	Living tissue implant with electrical transponder marker	Knapp et al.	
5993395	Pressure transducer apparatus with disposable dome	Shulze	600/488
5999857	Implantable device telemetry system and method	Weijand et al.	
6021352	Diagnostic testing methods and apparatus for implantable therapy devices	Christopherson et al.	
6024704	Implantable medical device for sensing absolute blood pressure and barometric pressure	Meador et al.	600/486
6034296	Implantable bone strain telemetry sensing system and method	Elvin et al.	
6053873	Pressure-sensing stent	Govari et al.	
6053918	Apparatus and method for fastening an intramedullary nail to a bone	Spievack	
6074394	Targeting device for an implant	Krause	
6106476	Ultra miniature pressure sensor and guide wire using the same and method	Corl et al.	600/486
6113553	Telemetric intracranial pressure monitoring system	Chubbuck	
6115636	Telemetry for implantable devices using the body as an antenna	Ryan	
6117086	Pressure transducer apparatus with disposable dome	Shulze	600/488
6140740	Piezoelectric transducer	Porat et al.	
6159156	Pressure sensor for use in an artery	Van Bockel	
6162228	Device for magnetically targeting locking holes in	Durham	

	orthopedic hardware		
6174322	Occlusion device for the closure of a physical anomaly such as a vascular aperture or an aperture in a septum	Schneidt	
6181973	Anchoring structure for implantable electrodes	Ceron et al.	
6185464	Arrangement for planting an endocardial cardiac lead	Bonner et al.	
6214029	Septal defect occluder	Thill et al.	
6216029	Free-hand aiming of a needle guide	Paltieli	
6234973	Implantable medical device for sensing absolute blood pressure and barometric pressure	Meador et al.	600/486
6237398	System and method for monitoring pressure, flow and constriction parameters of plumbing and blood vessels	Porat et al.	
6239724	System and method for telemetrically providing intrabody spatial position	Doron et al.	
6240322	System and apparatus having low profile collapsible tines	Peterfeso et al.	
6259937	Implantable substrate sensor	Schulman et al.	
6261247	Position sensing system	Ishikawa et al.	
6277078	System and method for monitoring a parameter associated with the performance of a heart	Porat et al.	
6309350	Pressure/temperature/monitor device for heart implantation	VanTassel et al.	
6312465	Heart valve prosthesis with a resiliently deformable retaining member	Griffin et al.	
6328699	Permanently implantable system and method for detecting, diagnosing and treating congestive heart failure	Eigler et al.	
6328727	Transluminal anastomosis method and apparatus	Frazier et al.	
6370418	Device and method for measuring the position of a bone implant	Bernoski	
6374134	Simultaneous display during surgical navigation	Bladen et al.	
6385484	Spectroscopic system employing a plurality of data	Boksberger et	

	types	al.
6405091	Lead assembly with masked microdisk tip electrode and monolithic controlled release device	Vachon et al.
6409674	Implantable sensor with wireless communication	Brockway et al.
6411842	Implant device for internal-external electromyographic recording, particularly for the in vivo study of electromotor activity of the digestive system	Cigaina et al.
6442413	Implantable sensor	Silver
20020052604	Bone nail targeting system	Simon et al.

Foreign References:

DE3011671	
DE3219558	
DE29909923	
EP0021451	Apparatus for detecting relative motion.
EP0053976	A DEVICE TO SENSE AND DETERMINE THE PRESSURE OF A FLUID
EP0420177	Device for wireless measurement of a local physical value.
EP0646365	Aortic graft, and method and apparatus for repairing an abdominal aortic aneurysm.
EP0897690	Pressure sensor for use in an artery
EP1004267	Implant device for internal-external electromyographic recording, particularly for the in vivo study of electromotor activity of the digestive system
EP1050265	Pressure/temperature/flow monitoring device for vascular implantation
EP1216655	Intracardiac pressure monitoring device
JP6070324	
WO/1983/003348	VASCULAR PROSTHESIS
WO/1993/002626	POSITION DETECTION
WO/1994/004938	POSITION LOCATION SYSTEM
WO/1996/005768	MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS
WO/1997/013467	PROBE FOR LOCATING HOLES IN ORTHOPAEDIC INTERNAL FIXATION DEVICES
WO/1997/033513	IMPLANTABLE BIOSENSING TRANSPONDER
WO/1999/017095	BIOSENSOR

WO/1999/033453	$i(R)-PROCYCLIDINE FOR TREATING URINARY INCONTINENCE
WO/1999/034453	PIEZOELECTRIC TRANSDUCER
WO/1999/034731	METHOD AND DEVICE FOR FIXATION OF A SENSOR IN A BODILY LUMEN
WO/1999/048419	IMPLANTABLE BLOOD GLUCOSE SENSOR SYSTEM
WO/2000/016686	IMPLANTABLE SENSOR WITH WIRELESS COMMUNICATION
WO/2000/032092	INTRALUMINAL MONITORING SYSTEM
WO/2000/074557	INTRAVASCULARLY IMPLANTABLE DEVICE
WO/2001/036014	MONITORING A HEART PERFORMANCE PARAMETER
WO/2002/038082	DEVICE FOR CONTROLLING, REGULATING AND/OR PUTTING AN ACTIVE IMPLANT INTO OPERATION

Other References:

European Search Report EP 01 31 0521 dated Mar. 19, 2002.
Dargie, Henry J. "Diagnosis and Management of Heart Failure", BMJ 1994;308:321-8.
Stevenson, LW & Perloff, JK "The Limited Reliability of Physical Signs for Estimating Hemodynamics in Chronic Heart Failure", JAMA 1989;261, No.6:884-888.
Chakko S et al. "Clinical, Radiographic, and Hemodynamic Correlations in Chronic Congestive Heart Failure: Conflicting Results May Lead to Inappropriate Care", AJM 1991;90:353-359.
Stevenson LW "Tailored Therapy Before Transplantation for Treatment of Advanced Heart Failure: Effective Use of Vasodilators and Diuretics", J Heart Lung Transplant 1991;10:468-76.
Stevenson LW et al. "Poor Survival of Patients with Idopathic Cardiomyopathy Considered Too Well for Transplantation", AJM 1987;83:871-876.
Steinhaus David M et al. "Initial Experience with an Implantable Hemodynamic Monitor", Circulation 1996;93No. 4:745-752.
Ohlsson A et al. "Continuous Ambulatory Haemodynamic Monitoring with an Implantable System", European Heart Journal 1998;19:174-184.
European Search Report EP 02253973 dated Mar. 21, 2003.

Primary Examiner: Walberg, Teresa

Assistant Examiner: Dahbour, Fadi H.

Attorney, Agent or Firm: Capezzuto, Louis J.

Claims:

What is claimed is:

1. A telemetric medical sensor for implantation in a patient's body for measuring a parameter therein, the sensor comprising: a housing; a membrane at one end of the housing, the membrane being deformable in response to the parameter; a microchip positioned within the housing and operatively communicating with the membrane for transmitting a signal indicative of the parameter, wherein the signal is a digital signal, the microchip comprising an array of photoelectric cells; an LED for transmitting light at the photoelectric cells; and a shutter connected to the membrane and moveable between the photoelectric cells and the LED in response to deforming of the membrane.

2. The sensor of claim 1, wherein the photoelectric cells are arranged in staggered rows.

3. The sensor of claim 2, wherein the array includes a reference photoelectric cell.

4. The sensor of claim 3, wherein the reference photoelectric cell is not blocked by the shutter.

5. The sensor of claim 4, wherein the microchip further comprises a plurality of comparators operatively connected to the photoelectric cells.

6. The sensor of claim 5, wherein the microchip further comprises a buffer operatively connected to the comparators for storing and transmitting the digital signal.

7. The sensor of claim 1, wherein the sensor further comprises an antenna operatively connected to the microchip.

8. The sensor of claim 7, wherein the antenna is located at the exterior of the housing.

9. The sensor of claim 7, wherein the sensor further comprises a plurality of anchoring legs resiliently attached to the housing for anchoring the sensor into tissue.

10. The sensor of claim 7, wherein the housing includes a notch in an outer surface thereon.

11. The sensor of claim 10, wherein the housing further includes a circumferential groove at the notch.

12. The sensor of claim 7, wherein the housing further includes a tapered end.

13. The sensor of claim 12, wherein the tapered end includes a piercing tip thereon.

14. The sensor of claim 13, wherein the tapered end further includes helical threads thereon.

15. The sensor of claim 7, wherein the antenna is made of wire.

16. The sensor of claim 15, wherein the wire comprises silver and platinum iridium.

17. The sensor of claim 16, wherein the antenna has 20-25 turns.

Description:

FIELD OF THE INVENTION

The present invention relates, in general, to telemetric medical devices. More particularly, the present invention relates to a novel telemetric medical system which is capable of various medical applications including the measurement of a parameter within a patient's body, particularly an organ. One such application of the present invention is as an implantable telemetric endocardial pressure system, its associated novel components and their novel methods of use.

BACKGROUND OF THE INVENTION

In general, the use of implantable medical sensors in a patient is known. One example for an implantable sensor is disclosed in U.S. Pat. No. 4,815,469 (Cohen et al.) incorporated herein by reference. The disclosure is directed to an implantable medical sensor which determines the oxygen content of blood. The sensor includes a miniaturized hybrid circuit that includes light-emitting diode means, phototransistor means, and a substrate to which the light-emitting diode means and phototransistor means are bonded in a desired circuit configuration. The hybrid circuit is hermetically sealed within a cylindrical body made from a material that is substantially transparent to light, such as glass. Feedthrough terminals provide means for making an electrical connection with the hybrid circuit. The light-emitting diode means is driven with a stair-stepped current pulse. The purpose of the sensor is to sense the reflective properties of body fluid, such as blood, for spectrophotometric analysis. In one embodiment, the sensor is embedded within a bilumen pacemaker lead and positioned near the distal electrode of the lead so that the sensor resides within the heart when the lead is implanted within a patient, thereby allowing the sensed oxygen content of the blood within the heart to be a physiological parameter that can be used to control the pacing

interval of a rate-responsive pacemaker.

U.S. Pat. No. 5,353,800 (Pahndorf et al.) discloses an implantable pressure sensor lead having a hollow needle adapted to be screwed into a patient's heart. The pressure sensor is supplied electrical power through conductors in the sensor.

There are cases where permanent positioning of the sensor is needed. One such case, for example, is disclosed in U.S. Pat. No. 5,404,877 (Nolan et al.), which is incorporated herein by reference. A leadless implantable cardiac arrhythmia alarm is disclosed which continuously assesses a patient's heart function to discriminate between normal and abnormal heart functioning and, upon detecting an abnormal condition, generates a patient-warning signal. The alarm is capable of sensing impedance measurements of heart, respiratory and patient motion and, from these measurements, generating an alarm signal when the measurements indicate the occurrence of a cardiac arrhythmia. It is important to note that the sensor uses an antenna system having a coil inductor for generating an electromagnetic field into tissue for detecting changes in impedance which relate to a physiological phenomena. For example, the size of the inductor is preselected in order to match the dimensions of the organ or structure to be measured.

There are also several known implantable devices that employ telemetry for transmitting or receiving data from an external device. One such device is, for example, the system disclosed in U.S. Pat. No. 6,021,352 (Christopherson et al.). The device utilizes a pressure sensor as a transducer for sensing respiratory effort of the patient. Respiratory waveform information is received by an implantable pulse generator (IPG)/simulator from a transducer and inspiration synchronous simulation is provided by the IPG.

One other telemetric implantable device is disclosed in U.S. Pat. No. 5,999,857 (Weijand et al.). This reference discloses a telemetry system for use with implantable devices such as cardiac pacemakers and the like, for two-way telemetry between the implanted device and an external programmer. The system employs oscillators with encoding circuits for synchronous transmission of data symbols in which the symbols form the telemetry carrier. The system provides circuits for higher density data encoding of sinusoidal symbols, including combinations of BPSK, FSK, and ASK encoding. Embodiments of transmitters for both the implanted device and the external programmer, as well as modulator and demodulator circuits, are also disclosed. It is important to note that the implant device has its own power supply in the form of a battery for powering all of the circuitry and components of the implanted device.

It is also important to note, that to date, there has not been any telemetric medical system that is both a highly efficient system due

to its components and their ease of use while providing extremely accurate information regarding a measured parameter in a patient's body.

SUMMARY OF THE INVENTION

The present invention is directed to a novel telemetric medical system for use with various medical applications such as monitoring medical conditions or measuring parameters within a patient's body for different types of organs, including tissue, as well as their function.

The present invention is a telemetric medical system comprising a telemetric medical sensor for implantation in a patient's body for measuring a parameter therein. The sensor comprises a housing, and a membrane at one end of the housing, wherein the membrane is deformable in response to the parameter. A microprocessor, which is in the form of a microchip, is positioned within the housing and operatively communicates with the membrane for transmitting a signal indicative of the parameter.

A signal reading and charging device is locatable outside of a patient's body and communicates with the sensor. The signal reading and charging device comprises a casing and a circuit within the casing. The circuit comprises a logic control unit and a processing unit operatively connected to the logic control unit. The logic control unit, through a deep detector, receives the transmitted signal from the sensor. The logic control unit also sends a powering signal to the sensor through a sine wave driver for remotely powering the sensor. The powering signal is a sinusoidal wave signal approximately 4-6 MHz. The processing unit includes an algorithm for converting the transmitted signal received from the sensor into a measured parameter. Additionally, the signal reading and charging device includes a power source operatively connected to the circuit and a power switch for activating and deactivating the device.

The signal reading and charging device also includes an antenna coil for sending the powering signal to the sensor and for receiving the transmitted digital signal from the sensor. The antenna coil has inductive coupling with the sensor. The signal reading and charging device also includes a display, which is an LCD screen, for displaying the measured parameter.

The microprocessor, which is in the form of a microchip, comprises an array of photoelectric cells which are arranged in staggered rows. The array also includes a reference photoelectric cell located at one end of the array. A light emitting diode (LED)

transmits light at the photoelectric cells and the reference photoelectric cell.

The sensor further comprises a shutter connected to the membrane and moveable between the photoelectric cells and the LED in response to the deforming of the membrane. The sensor is arranged such that the reference photoelectric cell is not blocked by the shutter and remains exposed to the light emitted by the LED.

The microchip further comprises a plurality of comparators operatively connected to the photoelectric cells and a buffer operatively connected to the comparators for storing and transmitting the digital signal. The sensor further comprises an antenna, in the form of a coil, operatively connected to the microchip wherein the antenna is located at the exterior of the housing. Alternatively, the antenna is located within the housing of the sensor. Preferably, the antenna coil is made of wire comprising silver and platinum iridium. Additionally, the antenna has 20-25 turns.

The sensor according to the present invention further comprises a plurality of anchoring legs resiliently attached to the housing for anchoring the sensor into tissue. Additionally, the housing optionally includes a notch in an outer surface of the housing to facilitate deployment. The housing further optionally includes a circumferential groove at the notch to further facilitate deployment.

In another embodiment for the sensor, the housing further includes a tapered end and a piercing tip thereon. The tapered end further includes helical threads thereon for threading the sensor housing directly into tissue. An alternative embodiment includes a plurality of tissue barbs on the tapered end for anchoring the sensor housing directly into tissue.

The present invention also includes a method for telemetrically measuring a parameter in a patient's body comprising the steps of providing a telemetric medical sensor comprising a housing having a membrane at one end of the housing wherein the membrane is deformable in response to the parameter, and a microchip is positioned within the housing and operatively communicates with the membrane for transmitting a signal indicative of the parameter. The sensor is implanted at a site within the patient's body and the parameter is telemetrically measured from outside of the patient's body with a signal reading and charging device. The method also includes telemetrically powering the sensor from outside of the patient's body with the signal reading and charging device. The measured parameter is then displayed on the display of the signal reading and charging device.

The method according to the present invention also includes a

method for telemetrically measuring a parameter in a patient's heart wherein the method comprises the steps of imaging the heart, through the use of transesophageal ultrasonic imaging, and identifying an implantation site in the heart. An opening is created in the tissue at the implantation site and a sensor comprising a housing, a membrane at one end of the housing wherein the membrane is deformable in response to the parameter, and a microchip positioned within the housing and operatively communicating with the membrane for transmitting a signal indicative of the parameter is provided. The sensor is placed within the opening and the parameter is telemetrically measured from outside of the patient's body based on the transmitted signal by the sensor.

The method also includes telemetrically powering the sensor from outside of the patient's body and displaying the measured parameter with a signal reading and charging device. Parameter measurements are made multiple times per second with the signal reading and charging device.

According to the present invention, the sensor is positioned within a chamber of the heart by using the septum as an implantation site, for instance, the fossa ovalis. Alternatively, the sensor is positionable at other anatomical sites within the heart and other organs and tissue.

One parameter that is measured with the system and method according to the present invention is hemodynamic blood pressure in a chamber of the heart.

Accordingly, the method according to the present invention further includes taking between 10-20 parameter measurements per second.

Moreover, the method further includes creating the opening in the tissue with a needle. In one embodiment of the present invention, the sensor includes a plurality of anchoring legs on the sensor for anchoring the sensor to the tissue. Additionally, the sensor is coated with a nonthrombogenic agent in order to prevent thrombosis within the heart upon implantation of the sensor.

Another embodiment of the method according to the present invention includes a method for telemetrically measuring a parameter in a patient's heart wherein the method comprises the steps of imaging the heart with transesohageal ultrasonic imaging and identifying an implantation site in the heart. A sensor comprising a housing and a membrane at one end of the housing wherein the membrane is deformable in response to the parameter and a tapered distal end and piercing tip at the other end of the housing is provided. The sensor further comprises a microchip positioned within the housing and operatively communicating with

the membrane for transmitting a signal indicative of the parameter. The sensor is implanted at the site with the piercing tip and the tapered distal end of the sensor. The parameter is telemetrically measured from outside of the patient's body based on the transmission signal by the sensor. Additionally, the sensor is telemetrically powered from outside of the patient's body. A signal reading and charging device is used outside of the patient's body to measure the parameter, power the sensor, and display the measured parameter. Accordingly, parameter measurements are made multiple times per second with the signal reading and charging device.

The sensor is positioned within a chamber of the heart and the implantation site is the septum, for instance, at the fossa ovalis. With the system and method according to the present invention, one parameter that is measured is hemodynamic blood pressure within a chamber of the heart. For instance, 10-20 parameter measurements are made per second for monitoring blood pressure in accordance with the present invention.

Alternatively, the sensor includes helical threads on the tapered distal end of the sensor and the sensor is anchored into the tissue at the site by threading the tapered distal end of sensor directly into the tissue. Alternatively, the sensor includes a plurality of tissue barbs on the tapered distal end of the sensor and the sensor is anchored into the tissue at the site with the tissue barbs.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of a telemetric implantable medical sensor according to the present invention;

FIG. 2 is a top view of the sensor of FIG. 1 ;

FIG. 3 is a schematic illustration of an alternative embodiment of the sensor of FIG. 1 having a tapered distal end with helical threads and tissue piercing tip for anchoring into tissue;

FIG. 4 is another alternative embodiment of the sensor of FIG. 1 having a tapered distal end with tissue piercing tip and a plurality of tissue piercing barbs thereon;

FIG. 5 is a partial perspective view of the sensor of FIG. 1 with

some parts removed in order to reveal the internal components of the sensor;

FIG. 6A is schematic diagram illustrating a microprocessor circuit for the sensor according to the present invention;

FIG. 6B is a schematic diagram illustrating a logic circuit for the microprocessor circuit of FIG. 6A ;

FIG. 7 is a schematic illustration depicting an array of photoelectric cells for the sensor according to the present invention;

FIG. 8 is a schematic illustration depicting the telemetric system according to the present invention including the sensor of FIG. 1 and a signal reading and charging device remotely located from and in communication with the sensor;

FIG. 9 is a schematic diagram illustrating a read/charge circuit for the signal reading and charging device of FIG. 8 ;

FIG. 10 is a schematic illustration of a patient's heart; and

FIG. 11 is a schematic illustration depicting the sensor fully deployed within a tissue aperture according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to a novel telemetric medical system **30** , as schematically illustrated in FIG. 8 , as well as its novel components and methods of use useful for various medical applications, as explained and demonstrated herein.

One aspect of the system **30** of the present invention is to remotely sense and measure a characteristic or parameter (or number of various parameters including the magnitude of any parameter) within a patient's body, or within an organ or tissue of the patient's body, through the use of a novel implantable telemetric medical sensor **50** , which is completely wireless, and a novel signal reading and charging device **140** which operatively communicates with the sensor **50** .

Telemetric Sensor

As schematically illustrated in FIG. 1 , the sensor **50** comprises a housing **52** made of a biocompatible material such as polysilicon or titanium. The housing **52** preferably has a cylindrical shape although any type of shape for the housing **52** is acceptable. The housing **52** has an approximate length ranging between 4-5 mm and an approximate diameter ranging from 2.5-3 mm in diameter. The housing **52** can also be smaller, e.g. 3 mm in length and a 1-2 mm outer diameter. The housing **52** includes cylindrical walls that are approximately 250 μm in thickness. A flexible membrane **56** made of a deformable material is fixed to one end of the housing **52** . A notch **58** and a circumferential groove **60** are provided on an exterior surface of the housing **52** for facilitating delivery and implantation of the sensor **50** .

The membrane **56** is made of a flexible or deformable material such as polysilicon rubber or polyurethane. The membrane **56** has an approximate thickness of 20 μm and has a diameter ranging from approximately 1.5-2 mm. The membrane **56** is normally biased outwardly from the housing **52** due to the interior pressure within the housing **52** . The membrane **56** is forced to bulge inwardly into the housing **52** whenever the pressure exterior of the housing **52** exceeds the internal pressure within the housing **52** .

Since the membrane **56** is deformable and normally biased outwardly from the housing **52** , the membrane **56** responds directly to the environment of the tissue or organ being monitored and/or measured for a particular characteristic or parameter. In response to even the slightest changes in these characteristics or parameters, the membrane **56** deforms inwardly toward the interior of the housing **52** . Accordingly, there is a direct relationship or correspondence between any change in measured characteristic or parameter and the amount or degree of deforming action or movement of the membrane **56** .

It is important to note that the membrane **56** has a relatively large area in dimension when compared to solid state membrane devices, such as piezoelectric sensors or fabricated memory chips utilizing membranes. Accordingly, the requirements from the electronics of the sensor **50** are less demanding. Additionally, the membrane **56** has a much larger deflection than that of the solid state membrane.

The sensor **50** also includes an antenna coil **68** which is operatively connected to the internal components of the sensor **50** by an antenna lead **70** . The antenna coil **68** is an inductance coil having a spiralled coil configuration. The material used for the antenna wire is approximately 90% silver content with a cladding of platinum iridium of approximately 10% content. The antenna coil **68** is preferably made of 20-25 turns of 30 μm thickness wire. The antenna outer diameter is 1.5-2.0 cm (FIG. **2**).

Accordingly, due to these features, the antenna coil **68** possesses a

very low parasitic capacitance. Additionally, the antenna coil **68** , due to its silver/platinum content wire has extremely high conductivity and is extremely flexible.

Although antenna **68** is described as being external of the housing **52** , it is well within the scope of the invention to include any type of suitable antenna, such as an antenna that is contained within the housing **52** .

The sensor **50** further includes anchoring legs **64** resiliently biased to the exterior of the housing **52** . The number of anchoring legs **64** can vary depending on the desired degree of anchoring and geography of the anatomy in which the sensor **50** is to be placed. The anchoring legs **64** are made from wire utilizing shape memory metal material, such as a nickel titanium alloy (NiTinol). The anchoring legs **64** have a concave configuration with a radius of curvature that curves into the tissue or organ in which the sensor **50** is to be anchored. Other appropriate configurations for the anchoring legs **64** are also contemplated herein.

If desireable, the sensor **50** is coated with a nonthrombogenic or anticoagulating agent such as Heparin prior to implantation in order to prevent thrombosis, clotting, etc.

FIG. 3 illustrates an alternative embodiment of the sensor **50** having a tapered end **54** on the housing **52** . The tapered end **54** has a tissue piercing tip **55** and helical threads **57** arranged on an outer surface of the tapered end **54** in order to facilitate the direct anchoring of the tapered end **54** of the housing **52** through direct threading into tissue.

FIG. 4 illustrates another alternative embodiment sensor **50** including a plurality tissue barbs **59** fixed to the tapered end **54** of the housing **52** . The barbs **59** have a tissue piercing tip curved outwardly away from the tissue piercing tip **55** . Accordingly, along with the tissue piercing tip **55** , the tissue barbs **59** grasp firmly into the tissue for firmly anchoring the housing **52** in the tissue.

As shown in FIG. 5 , the interior of the housing **52** includes a microprocesser **90** , in the form of a microchip, fixed within one of the interior walls of the housing **52** . The lead **70** of the antenna coil **68** is operatively connected to the microprocessor **90** . Microprocessor **90** includes an array **92** of photoelectric cells **95** arranged in a patterned confirguration, e.g. eight staggered rows containing eight photoelectric cells **95** in each row. A reference photoelectric cell **97** is located at one end of the array **92** resulting in an array **92** having a total of sixty-five photoelectric cells such as illustrated in FIG. **7** . The photoelectric cell array **92** provides for 64 degrees of resolution. The pitch distance between each photocell **95** is approximately ¼ the size of a photocell **95** .

Additionally, the reference photocell **97** has a dimension that is approximately the size of the pitch, e.g. ¼ the size of a photocell **95** , thus providing a resolution that is equal to a motion of ¼ of the photocell.

A light emitting diode (LED) **100** is operatively connected to the microprocessor **90** and is positioned above and spaced parallel and away from the photoelectric cell array **92** . A shutter **62** is connected to the inner surface of the membrane **56** and extends logitudinally from the membrane **56** within housing **52** . The shutter **62** has a substantially D-shaped configuration and logitudinally extends between the LED **100** and the photoelectric cell array **92** . The shutter **62** is made from an aluminum alloy and is positioned such that the planar surface of the shutter **62** directly faces the photoelectric cell array **92** . The shutter **62** is fixed to the deformable membrane **56** such that the shutter **62** moves in association with the membrane **56** . Accordingly, when the membrane **56** is deflected inwardly into the housing **52** (due to the monitored or measured tissue or organ parameter), the shutter **62** logitudinally extends over a number of photoelectric cells **95** in the array **92** in direct relation to the inward movement of the membrane **56** as it is being deformed. Likewise, when the membrane **56** is deflected outwardly from the housing **52** , the shutter **62** moves logitudinally outwardly from the end of the housing **52** along with the membrane **56** . Accordingly, the shutter **62** obscures or blocks a number of the photoelectric cells **95** in accordance with the degree of movement of the membrane **56** . Thus, when the shutter **62** is positioned over a specific number of photoelectric cells **95** , light from the LED **100** is prevented from reaching the photoelectric cells **95** and affects signal transmission from these cells **95** . This arrangement constitutes an analog-to-digital (A/D) conversion which is power effective since there is a simple counting of the number of photocells that are on or off as a measure of the shutter's motion. Hence, the analog-to-digital conversion. Accordingly, the microprocessor **90** operatively communicates with the membrane **56** .

The reference photoelectric cell **97** is never obscured or covered by the shutter **62** since it is located at the far end (end away from the membrane **56**) of the array **92** . The shutter **62** and membrane **56** are calibrated such that even upon maximum deflection inwardly into the housing **52** , it results in the reference photoelectric cell **97** being permanently exposed to the LED **100** for use as a reference signal for the sensor **50** . Yet, the power dissipation of the photocell is very low.

As best shown in FIG. 6A , the microprocessor **90** is a circuit wherein the antenna coil **68** and a resonance capacitor **102** operate as a resonating oscillator for the sensor **50** . The antenna coil **68** receives transmitted RF signals sent by the signal reading and charging device **140** as illustrated in FIGS. 8 and 9 . The RF signal

received at the antenna coil **68** is a charging signal for powering the microprocessor **90** . Upon receiving the RF charging signal, the antenna coil **68** and capacitor **102** resonate and charge a charge capacitor **114** through diode **116** . Upon reaching a predetermined voltage threshold of approximately 1.2 V, the capacitor **114** powers the LED **100** and a logic circuit **91** through control unit **104** . Upon powering of the LED **100** by the charged capacitor **114** , the LED emits light to the photoelectric cell array **92** which is kept at negative voltage.

As illustrated in FIG. 6B , the photoelectric cell array **92** is designated P_1 , P_2 , . . . P_{64} and P_{ref} , respectively. Each photoelectric cell **95** (P_1 -P_{64}) are connected in parallel to a plurality of comparators **120** designated C **1** , C **2** . . . C **64** . The reference photoelectric cell **97** is operatively connected to each comparator **120** (C **1** -C **64**) for providing a reference signal to each comparator **120** in comparison to the signal received from each respective photoelectric cell **95** . The logic circuit **91** is powered and controlled by the control unit **104** and a clock **106** . The control unit **104** is connected to each comparator **120** .

A buffer **126** having a plurality of buffer cells **129** (sixty-four total buffer cells corresponding to each comparator C **1** -C **64**) is operatively connected to the comparators **120** . Each buffer cell **129** is a flip-flop, or memory cell, which receives a signal from its respective comparator C **1** -C **64** resulting in a binary number which is sixty-four digits long (a series of ones or zeros). All buffer cells **129** are filled in a single clock cycle and each buffer **129** has either "0" or "1" in it. After all sixty-four buffer cells **129** have been filled with its respective binary number, the digital signal representing all sixty-four bytes is sent to the signal reading and charging device **140** by the control unit **104** . After transmitting the digital signal, the control unit **104** is reset by the clock **106** awaiting further signal inputs from the signal reading and charging device **140** . Encryption of the binary number is provided by the signal reading and charging device **140** described in greater detail below.

Upon filling the sixty-fourth buffer cell, the digital signal is transmitted from the buffer **126** and activates switch **112** resulting in a transmission of the digital signal from the antenna coil **68** to the antenna coil **162** of the signal reading and charging device **140** .

One main aspect of the system **30** of the present invention is that the sensor **50** is both a wireless transponder and a low-powered device capable of fast update rate, despite its passive nature, due to the inherent analog-to-digital (A/D) conversion mechanism employed in the sensor **50** , e.g. the photoelectric cell array **92** , which directly converts the membrane **56** deflection into a digital

signal, with no power consumption as would be required for a conventional electronic A/D converter.

Signal Reading and Charging Device

As illustrated in FIG. 8 , the signal reading and charging device **140** according to the present invention is for use outside of a patient's body or at the exterior surface of the patient's body. The signal reading and charging device **140** includes a casing **145** , which is a housing, having a liquid crystal display (LCD) display screen **172** mounted in an opening in the housing **145** . The signal reading and charging device, also commonly referred to as a read/charge device, reader/charger or reader/charger device, is activated by a power switch or toggle **146** extending from the casing **145** . Antenna coil **162** operatively communicates with the antenna coil **68** of the sensor **50** by inductance coupling.

As shown in FIG. 9 , once the logic circuit **91** transmits the digital signal from the sensor **50** through sensor antenna coil **68** , the coupling constant of the reader/charger antenna coil **162** is changed and is detected by a deep detector **168** operatively connected to the reader/charger antenna coil **162** . The deep detector **168** is sensitized to detect a change in the amplitude of the signal for as low as a 0.01% change in amplitude.

A read/charge logic control unit **154** is operatively connected to the deep detector **168** for determining the threshold for the deep detector **168** . The logic control unit **154** also includes a power source **151** for powering the components of the reader/charger device **140** .

The reader/charger circuit **150** further includes a processing unit **170** operatively connected to the logic control unit **154** . The processing unit **170** contains the algorithm for converting the digital signal received from the sensor **50** (FIG. 8) into a measured parameter for the medical parameter, condition or characteristic sensed at the implanted sensor **50** . Additionally, the processing unit **170** includes encryption code for encryption of the digital signal (sixty-four bit signal) using encryption algorithms such as exclusive-OR (XOR), RSA methods (RSA Security, Inc.), etc.

For example, where the parameter being measured is hemodynamic blood pressure, within an organ such as the chamber of a heart, once the processing unit **170** receives the digital signal, the processing unit **170** , through its algorithm, converts the digital signal (binary number) to a pressure value, using a look-up comparison table, or analytical expression representing the relation between the shutter **62** deflection in the sensor **50** versus the exterior sensor pressure at the membrane **56** , which is given below:

$$P = (KD^3/A^2)X^2$$

where P is the pressure value, D is the thickness of the membrane, A is the membrane radius, X is the deflection from the equilibrium and K is a constant.

The LCD display **172** is operatively connected to the processing unit **170** for displaying the measured parameter (hemodynamic blood pressure in the example above) converted from the digital signal in real time.

By utilizing the signal reading and charging device **140** at the exterior of the patient's body, continuous parameter readings (for determining aspects of the parameter such as magnitude) are obtainable for both the mean and active or individual values of the sampled parameter.

When measuring characteristics of a body fluid such as blood, the signal reading and charging device **140** maintains an active reading volume around the sensor **50** , ranging anywhere from 5-25 cm, and preferably, an active reading volume ranging approximately 10-15 cm. Moreover, with the telemetric medical system **30** , through the sensor **50** , and the signal reading and charging device **140** , it is possible to sample multiple readings per second. Preferably, approximately 10-20 readings per second are possible with the present invention.

Other attributes associated with the present invention when utilized as a pressure monitor in a chamber of the heart include monitoring a pressure range of +/−30 mmHg; an accuracy (at 5 mSec. integration) of +/−1 mmHg with a repeatability (at 5 mSec. integration) of +/−1 mmHg. It is important to note that the pressure boundaries can be changed easily by changing the size and dimensions, such as width, of the membrane without any change to the electronics. This is important for allowing the present invention to be adapted for various applications while using the same design.

The control unit **154** is also operatively connected to a sine-wave driver **158** for generating a sinusoidal wave signal of approximately 4 to 6 MHz. The sinusoidal wave signal is generated by the sine-wave driver **158** through capacitor **160** to the reader/charger antenna coil **162** for transmission or sending to the antenna coil **68** of the sensor **50** in order to power or charge the sensor **50** as described above.

Medical Procedures

As mentioned above, the telemetric medical system **30** according to the present invention is useful for nearly any type of medical diagnostic procedure where it is desireable to implant the sensor **50**

at a portion of the body, particularly tissue or organ of interest. The telemetric medical system **30** according to the present invention allows for remote monitoring and diagnosis of a condition of the tissue or organ by being able to rapidly sample various parameters or variables of any physical condition within the patient's body at the site of interest. Since the telemetric medical system **30** is wireless, these types of procedures are conducted in a completely non-invasive manner with minimal trauma to the patient.

One particular example for the telemetric medical system **30** according to the present invention, its components and their method of use, is in the field of congestive heart failure (CHF). CHF is defined as a condition in which a heart **400** (FIG. 10) fails to pump enough blood to the body's other organs. This can result from narrowed arteries that supply blood to the heart muscle (due to coronary artery disease), past heart attack, or myocardial infarction, with scar tissue that interferes with the heart muscle's normal work, high blood pressure, heart valve disease due to past rheumatic fever (in valves such as semilunar valve, tricuspid valve **417** or mitral valve **418**) or other causes, primary disease of the heart muscle itself, called cardiomyopathy, defects in the heart present at birth such as congenital heart disease, infection of the heart valves and/or heart muscle itself (endocarditis and/or myocarditis).

The ailing heart **400** keeps functioning but not as efficiently as it should. People with CHF cannot exert themselves because they become short of breath and tired. As blood flowing out of the heart **400** slows, blood returning to the heart **400** through the veins backs up, causing congestion in the tissues. Often swelling (edema) results, most commonly in the legs and ankles, but possibly in other parts of the body as well. Sometimes fluid collects in the lungs and interferes with breathing, causing shortness of breath, especially when a person is lying down. Heart failure also affects the ability of the kidneys to dispose of sodium and water. The retained water increases the edema.

CHF is the most common heart disease in the United States and it is estimated that over 5 million patients suffer from it. One of the more predictive hemodynamic parameters being measured in patients with CHF is blood pressure in the left atrium **410** , e.g. left atrial (LA) pressure. To date, this parameter is measured by employing invasive right heart catheterization with a special balloon catheter such as the Swan-Gantz catheter.

Accordingly, in moderating for effects of CHF, it is desireable to measure the blood pressure in a particular chamber (either right atrium **415** , right ventricle **419** , left atrium **410** or left ventricle **420**) in the heart **400** utilizing the telemetric medical system **30** according to the present invention.

Accordingly, in conducting one preferred method according the present invention, blood pressure can be directly monitored in the left atrium **410** of the heart **400** . Accordingly, it is desireable to implant the sensor **50** at fossa ovalis **407** within the septum **405** .

With respect to the specific anatomy of the septum **405** , in approximately 15% of the normal population, the fossa ovalis **407** has a pre-existing hole or opening that either remains open or patent and is normally covered by a small flap of tissue. In approximately 85% of the normal population, the fossa ovalis **407** is completely occluded, e.g. there is no hole in the septum **405** .

(1) Transcatheter Approach

In accordance with the method according to the present invention, a transcatheter approach has been found to be particularly useful for the patient population already having the pre-existing hole at the fossa ovalis **407** . Accordingly, in performing this method according to the present invention, first, a transesophageal ultrasonic probe (not shown) is inserted into the patient's mouth and placed in the esophagus. In most cases, the transesophageal ultrasonic probe is positioned approximately 30-35 cm from the mouth, i.e. in most cases positioned just above the patient's stomach.

Under transesophageal ultrasonic guidance, a wire (not shown) is inserted into the right atrium **415** through an appropriate vessel such as the inferior vena cava **408** wherein the wire is guided through the fossa ovalis **407** by gently lifting the tissue flap away from the patent opening at the fossa ovalis **407** . Once the wire is inserted through the fossa ovalis **407** , the wire is guided to one of the pulmonary veins **416** for placement of the distal end of the wire in order to properly position and anchor the wire in the opening of the pulmonary vein **416** . Accordingly, the pulmonary vein **416** has been proven to be a very reliable and steady anchoring point for the wire.

Once the wire is properly positioned in the fossa ovalis **407** and anchored in the pulmonary vein **416** , a catheter sheath ("over-the-wire" type—not shown) is guided over the wire through the right atrium **415** and the fossa ovalis **407** and positioned within the left atrium **410** , for instance, very close to the opening of the pulmonary vein **416** .

Once the catheter sheath has been properly positioned, the wire is removed from the patient's heart **400** and the sensor **50** is delivered through the catheter sheath by one of the many standard catheter-based delivery devices (not shown). Accordingly, the sensor **50** can be delivered to the fossa ovalis **407** by any of the typical catheter-based delivery devices normally associated with implantable pacemakers, electrodes, atrial septal defect (ASD)

occlusion devices, etc. Accordingly, the sensor **50** is deliverable with typical delivery devices such as the Amplatzer® Delivery System, manufactured by AGA Medical Corporation of Golden Valley, Minn.

After placement of the catheter sheath, the sensor **50** is deployed from the catheter sheath within the fossa ovalis **407** as best illustrated in FIG. **11** . Upon deployment, the sensor **50** utilizes the anchoring legs **64** for anchoring the sensor **50** to the septum **405** and occluding the opening at the fossa ovalis **407** .

(2) Anterograde Approach

The sensor **50** is placed in the fossa ovalis **407** for those patients not having a pre-existing opening in the fossa ovalis **407** through means of an anterograde approach. Once again, a transesophageal ultrasonic probe is positioned in the patient's esophagus as described above. Under transesophageal ultrasonic imaging guidance, an opening is made in the septum **405** at the fossa ovalis **407** in order to place and accommodate the sensor **50** . Thus, the opening is made with a standard needle catheter (not shown) such as the BRK™ Series Transseptal Needle manufactured by St. Jude Medical, Inc. of St. Paul, Minn. Accordingly, under transesophageal ultrasonic guidance, the needle catheter is initially placed in the right atrium **415** and positioned at the fossa ovalis **407** . At this point, the tip of the needle of the needle catheter penetrates the fossa ovalis **407** and the catheter is inserted through the fossa ovalis **407** into the left atrium **410** through the newly created opening in the fossa ovalis **407** by the needle catheter. Once the opening in the fossa ovalis **407** is created, the sensor **50** is introduced with the delivery device, such as the delivery device described above, and placed in the fossa ovalis opening as shown in FIG. **11** . Upon deployment of the anchoring legs **64** , the opening in the fossa ovalis **407** is occluded around the sensor housing **52** and the sensor **50** fixed to the septum **405** in a secure fashion.

It is important to note that transesophageal ultrasonic imaging is utilized for both the transcatheter and the anterograde approach as described above in accordance with each method step of the present invention. Since either method according to the present invention can be utilized with the transesophageal ultrasonic guidance, other imaging modalities such as flouroscopy can be eliminated. As such, the methods according to the present invention can be conducted in an outpatient clinic or doctor's office as a bedside procedure. By eliminating the need for a flouroscope, the method according to the present invention also eliminates the need for conducting the procedure in a catheter lab which only adds additional time and cost to the procedure and additional time and inconvenience to the patient.

After the sensor **50** has been implanted in the patient's septum **405** , the patient is provided with standard treatment to prevent excessive coagulation or endothelialization. For instance, it is common practice to prescribe aspirin and/or an anticoagulant such as Heparin for a period of time such as six months.

With either of the methods described above, the sensor **50** is fixed to the septum **405** in order to provide real time pressure monitoring in the left atrium **410** . Since the sensor **50** is a wireless transponder and a battery low power receiver, the sensor **50** does not impede the natural function of the heart **400** and is truly minimally invasive.

By utilizing the signal reading and charging device **140** at the exterior of the patient's body, continuous pressure readings are obtainable for both the mean and pulsating values of pressure in the left atrium **410** provided by the sensor **50** .

With the telemetric system **30** , the signal reading and charging device **140** maintains an active reading volume around the sensor **50** ranging anywhere from 5-25 cm, and preferably, an active reading volume ranging approximately 10-15 cm. Moreover, with the sensor **50** , and the signal reading and charging device **140** , it is possible to sample multiple readings per second. Preferably, approximately 10-20 readings per second are possible with the present invention.

Other attributes associated with the present invention when utilized as a pressure monitor in a chamber of the heart include monitoring a pressure range of plus/minus 30 mmHg; and accuracy (at five Mmsec. integration) of plus/minus 1 mmHg and a repeatability (at 5 msec. integration) of plus/minus 1 mmHg.

Although preferred embodiments are described hereinabove with reference to a medical system, devices, components and methods of use, it will be understood that the principles of the present invention may be used in other types of objects as well. The preferred embodiments are cited by way of example, and the full scope of the invention is limited only by the claims.

<- Previous Patent (Apparatus and method...) | Next Patent (System and method fo...) ->

- Home
- Search Patents
- Data Services
- Help
- Contact us